Proposed Re-evaluation Decision PRVD2017-02

Potassium Peroxymonosulfate

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Overview

What is the Proposed Re-evaluation Decision?

After a re-evaluation of the pesticide products containing potassium peroxymonosulfate, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing potassium peroxymonosulfate for sale and use in Canada.

An evaluation of available scientific information has found that products containing potassium peroxymonosulfate do not present unacceptable risks to human health or the environment when they are used according to the label directions. This proposal affects all pesticide products containing potassium peroxymonosulfate registered in Canada.

This Proposed Re-evaluation Decision (PRVD) is a consultation document[1] that summarizes the science evaluation for potassium peroxymonosulfate and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The Overview describes the regulatory process and key points of the re-evaluation, while the Science Evaluation provides detailed technical information on the assessment of potassium peroxymonosulfate.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment.

What is Potassium Peroxymonosulfate?

Potassium peroxymonosulfate is a commercial greenhouse surface and equipment disinfectant. It is registered for control of viruses, bacteria and fungi on pre-cleaned, hard, non-porous surfaces or on equipment in greenhouses. Potassium peroxymonosulfate is applied by mop, sponge, cloth, spray or pressure washer in greenhouses. Potassium peroxymonosulfate is not to be applied directly to plants, seeds or soil.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Potassium Peroxymonosulfate Affect Human Health?

Potassium peroxymonosulfate is unlikely to affect your health when used according to the label directions.

People could be exposed to potassium peroxymonosulfate by working as a mixer/loader/applicator, by entering treated greenhouses, or by using treated equipment. Based on the low toxicity of the active ingredient, and the required personal protective equipment specified on the label, exposure is not of concern under current conditions of use.

Residues of potassium peroxymonosulfate are not expected in food or drinking water.

Environmental Considerations

What Happens When Potassium Peroxymonosulfate is Introduced into the Environment?

Potassium peroxymonosulfate is registered only for greenhouse use and is considered to have a limited potential for environmental exposure when used as directed on the label. No direct exposure to the environment is expected. Exposure is not of concern.

Measures to Minimize Risk

Labels of registered pesticide products include instructions for use. The directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. No additional mitigation measures or label updates are proposed as a result of the re-evaluation.

What Additional Scientific Information is Required?

No additional data are required.

Next Steps

Before making a final re-evaluation decision on potassium peroxymonosulfate, PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on potassium peroxymonosulfate. PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

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[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

In Canada, the re-evaluation of potassium peroxymonosulfate was initiated on 23 July 2015. The potassium peroxymonosulfate technical registrants have indicated support for the re-evaluation of all products containing potassium peroxymonosulfate. Currently registered products containing potassium peroxymonosulfate are listed in Appendix I.

2.0 Use Description of Potassium Peroxymonosulfate

Potassium peroxymonosulfate is currently registered as a greenhouse disinfectant for control of viruses, bacteria and fungi. It acts by oxidizing sulfur bonds in proteins and enzymes, which causes ruption of the cell wall.

Potassium peroxymonosulfate is used in empty commercial greenhouses to disinfect surfaces (walls, ceilings and floors) and equipment such as trays, containers, utensils and vehicles. The product is used as a 1% w/v solution. For surface application, potassium peroxymonosulfate is applied using mop, sponge, cloth, spray or pressure washer. Equipment and utensils can be treated as required with sponge, cloth or sprayer. A minimum contact time of 10 minutes with surface is required for disinfection. Surface that may come in contact with foods must be rinsed with potable water following disinfection. The product is not to be applied directly to plants, seeds or soil.

3.0 The Technical Grade Active Ingredient and Its Properties

3.1 Identity of the Technical Grade Active Ingredient

Common Name Potassium peroxymonosulfate sulfate

Function Slimicide

Chemical Family Persulfate

Chemical Name

- International Union of Pure and Applied Chemistry (IUPAC):
  Pentapotassium bis(peroxymonosulphate)bis(sulfate)

- Chemical Abstracts Service (CAS):
  Potassium peroxymonosulfate sulfate

CAS Registry Number 70693-62-8

Registration Number 23137

3.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result	Interpretation
Vapour pressure at 25°C	Not applicable	Not applicable
Ultraviolet (UV) / visible spectrum	Not expected to absorb at λ >300 nm	Phototransformation is unlikely
Solubility in water	25.6 g/100g at 20°C 26.8 g/100g at 27°C 30.0 g/100 g at 49°C 31.5 g/100g at 60°C 33.5 g/100g at 71°C	Very soluble in water
n-Octanol/water partition coefficient	Not applicable	Not applicable
Dissociation constant	Not applicable	Not applicable

4.0 Human Health

Exposure to the potassium peroxymonosulfate may occur through working as a mixer/loader/applicator, or by entering treated sites. The active ingredient is not intended for use on food or in residential areas.

4.1 Toxicological Summary

Potassium peroxymonosulfate is of low acute toxicity via the oral, inhalation and dermal routes of exposure. It is considered to be corrosive to the eyes and skin. It is not a dermal sensitizer.

Potassium peroxymonosulfate is of low toxicity to humans. No developmental or reproductive effects or evidence of carcinogenicity have been identified.

4.2 Occupational Exposure and Risk

There is potential for dermal and inhalation exposure to workers while using disinfectant solutions containing potassium peroxymonosulfate. Workers may also be exposed when re-entering greenhouses and/or using treated equipment disinfected with potassium peroxymonosulfate. Occupational exposure is expected to be intermittent over a long-term duration.

Based on the low toxicity of potassium peroxymonosulfate, a qualitative risk assessment was conducted for worker exposure.

Potassium peroxymonosulfate is corrosive to the eyes and skin; therefore, it poses acute risk of

eye and skin irritation to mixers/loaders/applicators. These hazards are mitigated through the use of personal protective equipment specified on the current label including goggles, face shield or safety glasses, coveralls over long-sleeved shirt and long pants, boots and chemical-resistant gloves during mixing, loading, application and clean up and repair activities. No acute inhalation hazard is identified and respiratory protection is not required. Postapplication exposure is expected to be low based on the assumption that residues are not expected to contact plants and that no one enters/contacts treated surfaces until residues are dry.

Based on the current label directions, occupational exposure is not expected to be of concern. No additional mitigation measures are required.

4.3 Non-Occupational Exposure and Risk

Potassium peroxymonosulfate is used in empty commercial greenhouses and is not applied directly to plants, seeds or soil. The label requires food contact surface to be washed with potable water following the treatment with the active ingredient. On this bases, dietary (food and drinking water) exposure to potassium peroxymonosulfate is expected to be minimal and not of concern. Residential or bystander exposure to potassium peroxymonosulfate is not expected based on the current use pattern.

4.4 Cumulative Exposure and Risk

Potassium peroxymonosulfate has low toxicity to humans. No treatment related effects of toxicological concern have been identified. No common mechanism of toxicity applicable to humans or animals has been identified with other pest control products. Therefore, no cumulative risk assessment was conducted during the re-evaluation.

5.0 Environment

Potassium peroxymonosulfate when used inside commercial greenhouses is considered to have a limited potential for environmental exposure. The current label includes standard statements prohibiting effluent or runoff from greenhouses containing potassium peroxymonosulfate to enter lakes, streams, ponds or other waters.

Potassium peroxymonosulfate is toxic to birds and aquatic organisms. The active ingredient is a salt that contains a peroxy functional group, which makes it reactive; however, it readily oxidizes and breaks down in aqueous media. Potassium peroxymonosulfate degrades to known ions which are already present in the environment. Potassium peroxymonosulfate is not likely to persist.

Based on the current use pattern, risks to the environment are considered to not be of concern.

6.0 Value

Potassium peroxymonosulfate has value as a disinfectant for greenhouse hard-surfaces, equipment and utensils. It is one of three active ingredients currently registered in Canada specifically for this use. It is the only active ingredient registered for the control of viral plant pathogens.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy (TSMP) Considerations

Based on the available information, potassium peroxymonosulfate does not meet TSMP Track 1 criteria. The active ingredient dissipates rapidly in the environment and is not persistent.

Contaminants of Health or Environmental Concern

During the re-evaluation of diflufenzopyr-sodium, contaminants in the technical were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[3] The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol).

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the *Canada Gazette* are not expected to be present in the product.

8.0 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to PMRA within a set time frame. As of 27 February 2017, there are no incident reports in the Canadian database for potassium peroxymonosulfate.

9.0 Organisation for Economic Co-operation and Development

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments can work together to share experience and seek solutions to common problems. As part of the re-evaluation of an active ingredient, PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

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[3] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

Potassium peroxymonosulfate is currently acceptable for use in other OECD member countries, including the United States, Australia and European Union. As of 20 January 2017, no decision by an OECD member country to prohibit all uses of potassium peroxymonosulfate for health or environmental reasons has been identified.

10.0 Proposed Re-evaluation Decision

PMRA has determined that products containing potassium peroxymonosulfate for sale and use in Canada are acceptable for continued registration. No additional mitigation measures or label updates are required.

List of Abbreviations

w/v	weight/volume
CAS	Chemical Abstracts Service
IUPAC	International Union of Pure and Applied Chemistry
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Registered products containing potassium peroxymonosulfate as of 27 February 2017.

Registration Number	Product Name	Registrant	Formulation	Class	Guarantee
23137	OXONE MONOPERSULFATE COMPOUND	The Chemours Company FC, LLC	Soluble powder	Technical	KPM 43.0%
24210	VIRKON GREENHOUSE	Vétoquinol N.-A. Inc.	Soluble powder	Commercial	KPM 21.4%

References

Published Information

PMRA Document Number	Reference
2205599	Evaluation Report for Application Number 2012-0734

Unpublished Information

PMRA Document Number	Reference
1607983	Chemistry data used to support a Technical class product. KPM-DUZ-8, DACO: 2.99
1607984	Chemistry data used to support a Technical class product. KPM-DUZ-8, DACO: 2.99
1607987	1994, Part 2 - Chemistry - Oxone Monopersulfate Compound - Data Submission, DACO: 2.1,2.10,2.11,2.12,2.13,2.14,2.15,2.16,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
1607988	Part 2 - Chemistry - Oxone Monopersulfate Compound - Data Submission, DACO: 2.1,2.10,2.11,2.12,2.13,2.14,2.15,2.16,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
1607989	Part 2, Chemistry, DACO: 2.1,2.10,2.11,2.12,2.13,2.14,2.15,2.16,2.2,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
2669865	2009, TCI 1500 Process Overview & Block Flow Diagram (Revision #6 dated 20090824), DACO: 2.11 CBI
2669683	2016, Five Batch Analysis of Oxone(TM) Produced at [Privacy removed], DACO: 2.13.3 CBI
2669686	2009, CONFIDENTIAL- Composition and Spectral Confirmation of Pentapotassium bis(peroxymonosulfate) bi(sulfate) CAS No. 70693-62-8, DACO: 2.11.2.13.3 CBI
2669684	2016, [CBI removed] and Characterization of Oxone Samples, DACO: 2.13.3,2.13.4 CBI